

**STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY**

**CURRENT TRIAL STUDIES
as of 12/01/05**

Local EMS Agency	Study Title	EMS Agency Medical Director and Primary Investigator	Date of Initiation of Trial Study	Commission Notified	18 Mo. Report Due	Commission Action	36 Mo. Report Due	Disposition of Study
Nor Cal EMS	EMT-II Modular Trial Study (Sierra County) Study Modified on 10/10/04.	Chester Ward, MD Medical Director	8/16/01	9/26/01	2/28/03 4/30/06	On 3/19/03, Commission reviewed the 18-month report and recommended approval of an 18-month extension of the study. On 9/22/04 Commission approved an extension of the study until the EMT-I Regulations take effect, and recommended approval of a modification of the study to include only IV lines and administration of 50% dextrose once the EMT-I Regulations take effect. On 11/4/04 NorCal EMS submitted their modification of the Study to include only IV lines and administration of 50% dextrose, and the modification was acknowledged by EMSA on 11/18/04.	8/31/04	Modified on 10/10/04. Active until EMT-II Regs. are revised.
Imperial County EMS	EMT-II Modular Trial Study (formerly EMT-I with Advanced Skills)	Bruce Haynes, MD Medical Director	(1/96 for EMT-I)	(1/96 for EMT-I)	9/30/03 (7/31/97 for EMT-I)	9/24/97 voted to approve 18-month extension. Accepted 36-month report on 1/27/99 & recommended revising regulations to include use of the additional skills & medications by EMT-Is. Approved continuation of the study until the EMT-I regulations are revised. Emergency regulations took effect 4/16/01. On 6/20/01 Commission voted to allow regulation revisions to expire; recommended transition to EMT-II Modular Trial Study instead. On 12/9/03, the Commission recommended acceptance of the 18-month report and approval to continue the study for another 18 months. Commission recommended acceptance of the 36-month report on 6-22-05 & recommended continuation of the study until the EMT-II Regulations are revised.	3/31/05 (1/31/99 for EMT-I)	Active until EMT-II Regs. are revised.

San Diego County EMS/Los Angeles County EMS	Protocol Number RTBSE-11-(N): A Phase III, Randomized, Controlled, Open-Label, Multi-center, Parallel Grp Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety & Efficacy of Poly SFH-P Injection (Polymerized Human Hemoglobin (Pyridoxylated), Poly-Heme) When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting	Gary Vilke, MD, Medical Director for San Diego County; David Hoyt, MD, Primary Investigator for San Diego County.	5/23/04 for San Diego County	12/9/03	11/30/05	Request by Dr. Koenig in July 2004 to remove L.A. County from the study; request reported to the Commission on 9/22/04.		Active
inland Counties	EMT-I Advanced Scope of Practice	Conrad Salinas, MD, Medical	8/1/03	12/9/03	2/28/05	On 3/23/05, the Commission recommended modification of the study to include only IV access,	8/31/06	Active

		Director				dextrose 50%, determination of death, & clearance of spine/transport w/o immobilization w/more detailed data to include vital signs, skin signs, and mentation, as well as a summary of all skills & medications and focus on details of each skill or medication used.		
Los Angeles County	Field Administration of Stroke Therapy – Magnesium (FAST-MAG) Project	William Koenig, MD, Medical Director	1/1/04	12/9/03	9/31/05	The Commissioners reviewed the 18-month report at their 9/21/05 meeting.	3/31/07	Active
Central California	Treatment of Motion Sickness in the Prehospital Setting (Administration of Reglan)	Jim Andrews, MD, Medical Director	2/11/05	6/23/04	8/31/06			Active
Central California	Oversight of EMT-II Personnel	Jim Andrews, MD, Medical Director	10/1/04	9/22/04	4/30/06			Active
San Diego	Hypertonic Resuscitation Following Traumatic Injury	Gary Vilke, MD Medical Director		9/21/05		EMSA approval contingent upon approval by the FDA and the local investigative review boards of the 5 County trauma centers.		